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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,905	12/14/2001	Paul M. Ridker	B0801/7238 (ERG/KA)	7653

7590 02/08/2007

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/017,905	RIDKER ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,11,16,21,52,55,57,62-68 and 71-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,11,16,21,52,55,57,62-68 and 71-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 6, 11, 16, 21, 52, 55, 57, 62-68, and 71-76 are being acted upon.

2. Applicant's amendment and remarks of 12/04/06 are acknowledged.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 6, 11, 16, and 71-74 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As set forth previously, Applicant has no support in the originally filed claims or specification for the phrase "one or more" diabetic complications. The Examiner has reviewed where Applicant states they have support for such claim language in the response filed 1-30-06, but could not find it.

Applicant argues that support for the limitation can be found at pages 3 and 6 of the specification [in the remarks of 5/30/06].

A review of the specification reveals support for "a" complication at page 6. The cite at page 3, however, does not support the "or more" complications of the instant claims. While the cite does disclose "diabetic complications", the disclosure is not in the context of the method of the instant claims. The "diabetic complications" of page 3 are disclosed in the context of evaluating the likelihood that an individual will benefit from treatment and not in the context of characterizing a risk profile for developing diabetes as claimed.

Applicant now argues that support for the limitation can be found at page 4, lines 33-34 of the specification and in original Claim 1.

While page 4, lines 33-34 of the specification and original Claim 1 both disclose/recite the word "complications", in neither cite is the word used in the context of the instant claims. In neither cite is the term "one or more" used. In neither cite is the list of complications now recited in Claim 1 disclosed/recited.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 6, 11, 16, 21, 52, 55, 57, 62-68, and 71-76 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez-Moran et al. (1999).

As set forth previously, Rodriguez-Moran et al. teaches that elevated serum CRP levels have been found in type II diabetics and in diabetics with foot ulcers (see particularly page 211, column 2). The reference also teaches that elevated serum CRP levels are also found in noncontrolled type II diabetic patients. (see particularly Table 2). While the reference does not specifically teach characterizing a risk profile for developing diabetes or evaluating the likelihood that an individual will benefit from treatment, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made measure serum CRP levels for said uses given CRP's known association with type II diabetes, i.e., it is obvious to measure a known marker for the presence of, or predisposition to, a disease. Note that the choice of any particular serum CRP concentration as an indicator of disease comprises no more than routine optimization of the claimed method and falls well within the purview of the ordinarily skilled artisan.

Applicant's arguments, filed 12/04/06 have been fully considered but they are not persuasive. Applicant argues that "Rodriguez-Moran does not, and could not, address whether a level of CRP is predictive of developing diabetes … Rodriguez-Moran did not evaluate individuals who were apparently healthy (i.e., without diabetes). Instead, Rodriguez-Moran compared the serum levels of CRP in type II diabetic patients (i.e., after the diabetic disorder happened)."

Applicant's argument is, essentially, that the reference does not anticipate the claimed method. The Examiner agrees,

the reference does, however, render the claimed method obvious. It is well-established that undiagnosed diabetes comprises both a common and serious health threat to the population of the U.S. As set forth in the rejection, the screening for markers of a disease that routinely presents no symptoms for years would have been obvious to the ordinarily skilled artisan.

Applicant argues that the instant study was not designed to show that elevated CRP could predict diabetes.

Again, the argument is, essentially, that the reference does not anticipate the claimed method. Again, the Examiner agrees, however, given the often asymptomatic nature ("apparently healthy") of diabetes, the testing for known markers of the disease would have been obvious to the ordinarily skilled artisan.

Applicant argues that the reference teaches that elevated CRP is more likely the result of a diabetic condition rather than a cause of diabetes.

The point of Applicant's argument is unclear to the Examiner as the cause of elevated CRP is irrelevant - elevated CRP is simply a marker for type II diabetes. The reference teaches that noncontrolled type II diabetics display high CRP levels and as set forth above, it is well-established that many "apparently healthy" individuals actually suffer from type II diabetes, i.e., the individuals have noncontrolled diabetes.

7. Claims 1, 6, 11, 16, 21, 52, 55, 57, 62-68, and 71-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schalkwijk et al. (1999).

As set forth previously, Schalkwijk et al. teaches that elevated serum CRP levels have been found in type I diabetics and in diabetics with foot ulcers (see particularly page 211, **Results** and Table 2). While the reference does not specifically teach characterizing a risk profile for developing diabetes or evaluating the likelihood that an individual will benefit from treatment, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made measure serum CRP levels for said uses given CRP's known association with type I diabetes, i.e., it is obvious to measure a known marker for the presence of, or predisposition to, a disease. Note that the choice of any particular serum CRP concentration as an indicator of disease comprises no more than routine optimization of the claimed method and falls well within the purview of the ordinarily skilled artisan.

Applicant's arguments, filed 12/04/06 have been fully considered but they are not persuasive. Applicant's arguments are similar to those presented in traversal of the rejection in view of Rodriguez-Moran et al., i.e., that the reference does not anticipate the claimed invention.

As set forth above, while the reference does not anticipate the claimed method, it does render it obvious for the reasons set forth above in Section 6. And again, as set forth above, the cause of elevated CRP is irrelevant - elevated CRP is simply a marker for type I diabetes and can be used to characterize an apparently healthy, i.e., asymptomatic but suffering from the disease none the less, individual.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571)272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

11. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information

about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

2/05/07

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